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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/151,885	09/11/98	COSTIN	J 98-WL-1

004370
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HM12/0715

EXAMINER

LEE, H

ART UNIT

PAPER NUMBER

1623

DATE MAILED:

07/15/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/151,885

Applicant

Costin

Examiner

Howard C. Lee

Group Art Unit
1623

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-4 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-3 is/are rejected.

☒ Claim(s) 4 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

Howard C. Lee

Howard C. Lee
Primary Examiner
Art Unit 1623

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1623

Provisional Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 09/266,215. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims encompass the scope of the claims of '215.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Double Patenting Rejection

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

Art Unit: 1623

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 2 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 2 of copending Application No. 09/266,215. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

35 U.S.C. 112, first paragraph rejection

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

- (1) The quantity of experimentation necessary (time and expense);
- (2) The amount of direction or guidance presented;
- (3) The presence or absence of working examples of the invention;
- (4) The nature of the invention;
- (5) The state of the prior art;
- (6) The relative skill of those in the art;
- (7) The predictability or unpredictability of the art; and
- (8) The breadth of the claims.

The claim is directed toward a means of preventing bacteria to bacteria transfer of plasmid materials containing genes capable of resisting antibiotics. However, each of the examples provided in the specification are directed toward routine assays to test anti-bacterial activity and are not directed toward measuring transfer of plasmid material. Further, the assay conditions and

Art Unit: 1623

the disclosed means of administration do not differ from the conditions and administration methods previously known in the art. The state of the art is such that anti-bacterial activity is attributed to taurolidine but the mechanisms for explaining such activity has not been extended to transfer of plasmid materials and the specification has not shown that there is unexpected anti-bacterial activity attributed to such a mechanism or the differences in the treatment method which leads to this mechanism. Given the breadth of bacterial species encompassed by the scope of the claim, a skilled artisan would undergo great time and expense in terms of the experimentation necessary to practice the invention as claimed.

(Even if the applicant is able to show that there is a transfer of plasmid materials, given the description of the treatment and means of administration, this effect would be deemed to be an inherent property of the treatment methods previously disclosed in the art and the prior art rejections would remain. i.e. applicant cannot claim patentability for discovering a new mechanism for an old method of use.)

Improper multiple dependent claim

Claim 4 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim 4 not been further treated on the merits.

35 U.S.C. 103(a) rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1623

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Traub et al., (Chemotherapy, vol. 39: 322-330, (1993)).

The applicants' claims are directed toward:

- (a) the prevention of the development of antibiotic drug resistance in bacteria by administering taurolidine to a human or warm blooded animal (claim 1); and
- (b) preventing transfer of plasmid materials between bacteria by administering taurolidine (claim 2) which is interpreted for the purpose of this rejection as being like a limitation of claim 1 as the claimed material amounts to a mechanism for preventing drug resistance by bacteria.

Traub et al. discloses the use of taurolidine against clinical isolates of *Staphylococcus aureus*, *Enterococcus faecium* and various species of *Enterobacteriaceae* which are known to be resistant to a host of previously used antibiotics such as vancomycin. Traub et al. differs from the applicants claims in that the method of treatment is *in vitro* rather than *in vivo* and the combination of other antibiotics are not specifically disclosed.

However, both Traub et al. and the enabling examples provided in the specification are directed toward *in vitro* studies with the presumption that a skilled artisan would be able to practice the invention without undue experimentation. Furthermore, it is well known in the art that bacterial strains often develop a resistance to an antibiotic and that a regimen of an antibiotic

Art Unit: 1623

cocktail is necessary for full efficacy and as such the addition of one or more antibiotics to taurolidine would be a routine derivation of the claimed methods.

Therefore, one of ordinary skill in the art would have found the applicants claimed method for treating bacterial infections to have been obvious to one of ordinary skill in the art at the time the invention was made as Traub et al. teaches the efficacy of taurolidine against antibiotic resistant strains of bacteria.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Traub et al. as stated above in view of Blenkarn et al. (Surgical Res. Commun., vol. 2: 149-155, (1987).

Such that it may be argued that one of ordinary skill in the art would not be led to combine other antibiotics with taurolidine, Blenkarn et al. discloses the effects of the combination of taurolidine with other antibiotics (see Table 1 on page 151) against *S. aureus*, *E. coli*, *K. aerogenes*, *P. aeruginosa*, and *B. fragilis* (see "Bacterial Strains" section on page 150).

Examiner's hours, phone & fax numbers and other useful information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mr. Howard C. Lee whose telephone number is (703) 308-4626 and e-mail address is Howard.Lee@uspto.gov (NOTE: **The U.S PTO does not accept responsibility for the security of e-mail transmissions by the applicant(s).** Thus, e-mail sent to an examiner should not include confidential information. For further details, see the PTO Internet Usage Policy which has been published in the Federal Register of 21 June 1999, volume 64, number 118.) The examiner can normally be reached on Monday-Friday 0700-1530 (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Cecilia Tsang at (703) 308-0254 or Mr. Gary Jones at (703) 308-1152, may be contacted. The fax phone number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Art Unit: 1623

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more!

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Howard C. Lee
Primary Examiner
Art Unit 1623
14 July 1999